# Audit Report

**Global Standard for Food Safety Issue 8: August 2018**

## 1 Audit Summary

| | | | |
|---|---|---|---|
| Company name | Vion Boxtel BV | Site Code | 17768974 |
| Site name | Vion Boxtel BV | | |
| Scope of audit | The slaughtering of pigs, the deboning and cutting to specification and packing in bulk, bag in box, vacuum packaging and consumer packaging of pork | | |
| Exclusions from scope | The intestinal washing process | | |
| Justification for exclusion | Segregated process with clearly differentiated products | | |
| Audit Finish Date | 2020-07-30 | | |
| Re-audit due date | 2021-06-28 | | |

## Additional modules included

| Modules | Result | Scope | Exclusions from scope |
|---|---|---|---|
| Choose a module | Choose an item | | |
| Choose a module | Choose an item | | |

| | |
|---|---|
| Head Office | Yes |

## 2. Audit Results

| | | | | | |
|---|---|---|---|---|---|
| Audit result | Certificated | Audit grade | A | Audit type | Announced |
| Previous audit grade | A | Previous audit date | 2019-06-05 | | |
| Certificate issue date | Select a date | Certificate expiry date | Select a date | | |

| | | |
|---|---|---|
| Number of non-conformities | Fundamental | 0 |
| | Critical | 0 |
| | Major | 0 |

| | | |
|---|---|---|
| | Minor | 10 |

## 3 Company Details

| | | | |
|---|---|---|---|
| Address | Boseind 10<br>5528 RM Boxtel | | |
| Country | The Netherlands | Site Telephone Number | |
| Commercial representative Name | | Email | |
| Technical representative Name | | Email | |

## 4 Company Profile

| | | | | | |
|---|---|---|---|---|---|
| Plant size (metres square) | 10-25K sq.m | No. of employees | 501-1500 | No. of HACCP plans | 1-3 |

| | |
|---|---|
| Shift Pattern | 2 shifts Monday/Friday and incidentally 1 shift at Saturday |
| Subcontracted processes | No |
| Other certificates held | ISO9001, IFS PIA, BLK, IKB, QS, SQMS, Tesco approved |
| Regions exported to | Europe<br>Asia<br>Oceania<br>Africa<br>Choose a region<br>Choose a region |
| Company registration number | EG 61 NL |
| Major changes since last BRCGS audit | Investment project to enlarge the production process with the processing of middles (Boxtel stage 2 project), new plant manager, implementation of Covid 19 protocol, implementation of , preparation of , shelter in use for the covering of trucks with pigs especially during periods with temperatures > 25 C. |

## 4 Company Profile

Company Description

Vion Boxtel BV is the biggest processing plant of pigs to pork meat in the Netherlands. The company is part of the Vion Food group. The company is slaughtering about 19.o00 pigs per day in 2 shifts. Main customers are industrial meat processing companies in Europe, Asia and Australia. Snit ham are particularly produced for Spain and Italy. All pigs are bred by Dutch farmers and reared conform the Good Farming principles (IKB); a part of them are also reared regarding special Welfare demands (Good farming *). The company has a approved system to comply with dedicated welfare demands. The company has own employees and temporary workers (hired via contracted agencies). There's a 2-shift pattern. Most of the temporary workers are from East European countries such as Poland, Romania and Bulgaria. There are interpreters and job coaches in the company for communication purposes.
The company is certificated for ISO 9001 as part of a multi-site ISO system. Vion Boxtel is approved by authorities for export of pork meat to several third countries (e.g. Japan, Korea, Russia, Canada, Africa, China, Australia) The surface is 20.0 K sq. metres. The used quality system is based at HACCP-principles. The pork is packed at semi-bulk level and there are some vacuum-packed consumer goods for the Greek market. EG number is NL61 EG. Website: www.Vionfoodgroup.com. The site is audited against the requirements of BRC food 8; additional modules are not a part of the audit. Due to Covid 19 the current production level is decreased with 15%. There's an extensive Covid 19 protocol existing of a triage process before entering the site, modifications in internal logistic of people to maintain the 1.5 m distance, use of plastic screens at the cutting lines and other measures. The original audit was postponed due to Covid 19; a risk assessment is performed in June 2020. The HQ processes are not audited separately for BRC and integrated in the audit of the site.

## 5 Product Characteristics

| | |
|---|---|
| Product categories | 01 - Raw red meat<br>Category<br>Category<br>Category |
| Finished product safety rationale | Chilled red meat, short shelf life 5-8 days and chilled red meat vacuum packed, short shelf life 14-21 days |

| | | | | | |
|---|---|---|---|---|---|
| High care | No | High risk | No | Ambient high care | No |

| | |
|---|---|
| Justification for area | No high risk or high care production assigned on site. All products undergo full cooking prior to consumption |

## 5.Product Characteristics

| | |
|---|---|
| Allergens handled on site | None<br>Choose an allergen<br>Choose an allergen<br>Choose an allergen<br>Choose an allergen<br>Choose an allergen<br>Choose an allergen<br>Choose an allergen<br>Choose an allergen<br>Choose an allergen<br>Choose an allergen<br>Choose an allergen<br>Choose an allergen<br>Choose an allergen<br>Choose an allergen |
| Product claims made e.g. IP, organic | Welfare (GB = Good Farming Bacon) and BLK 1star (FS = Good Farming Star |
| Product recalls in last 12 Months | No |
| Products in production at the time of the audit | Mager Met 50/50, neck vacuum pack , Schoulder 4D F ), middles, snit ham Spain, snit ham Italy/pharma, tendon end , organs, tails,paws |

## 6. Audit Duration Details

| | | | |
|---|---|---|---|
| On-site duration | 24 man hours | Duration of production facility inspection | 16 man hours |
| Reasons for deviation from typical or expected audit duration | Simple processes with repetitive work | | |
| Next audit type selected | Announced | | |

## Audit Duration per day

| Audit Days | Audit Dates | Audit Start Time | Audit Finish Time |
|---|---|---|---|
| 1 (start date) | 2020-07-28 | 08.30 | 17.00 |
| | 2020-07-29 | 08.30 | 17.00 |
| | 2020-07-30 | 08.30 | 16.30 |

| | Auditor (s) number | Name | Role |
|---|---|---|---|
| Auditor Number | | | Lead Auditor |
| Second Auditor Number | N/A | | Please select |

## Present at audit

| Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings (ref: clause 1.1.11)<br>Name / Job Title | Opening Meeting | Site Inspection | Procedure Review | Closing Meeting |
|---|---|---|---|---|
| ; plant manager | x | | x | x |
| ; QA manager | x | x | x | x |
| QA employee | x | x | x | x |
| HR manager | x | | x | x |

| Present at audit | | | | |
|---|---|---|---|---|
| manager internal logistics | x | | | |
| manager cutting/veredeling | x | x | | x |
| manager slaughtering | x | | | |
| manager planning | x | | | |
| assistent manager maintenance | x | x | x | x |
| manager facility management | | | x | |
| manager slaughtering department | | | x | |
| Several operators and supervisors of the production departments | | | x | |

| GFSI Audit History | | |
|---|---|---|
| Date | Scheme/Standard | Announced/Unannounced |
| | none | |

# Non-Conformity Summary Sheet

| Critical or Major Non-Conformities Against Fundamental Requirements | | | | |
|---|---|---|---|---|
| No. | Requirement ref. | Details of non-conformity | Critical or Major? | Anticipated re-audit date |
| | | | | |
| | | | | |
| | | | | |

| Critical | | | |
|---|---|---|---|
| No. | Requirement ref. | Details of non-conformity | Anticipated re-audit date |
| | | | |
| | | | |
| | | | |

| Major | | | | | | | |
|---|---|---|---|---|---|---|---|
| No. | Requirement ref. | Details of non-conformity | Correction | Proposed preventive action plan | Root cause analysis | Date reviewed | Reviewed by |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

| Minor | | | | | | | |
|---|---|---|---|---|---|---|---|
| No. | Requirement ref. | Details of non-conformity | Correction | Proposed preventive action plan | Root cause analysis | Date reviewed | Reviewed by |
| 01 | 2.8.1. | CP 31/32 are related to growth of pathogens based at high temperature due to long residence time of meat/organs at the production departments. For site Boxtel there's a organ chilling process; temperature checks are done to verify the chilling process. In case of deviations the | Procedures and the forms F-BXT-NL-10161, F-BXT-NL-10189 with "Te warme producten blokkeren tot aan vorige goede temperatuurmeting" are adjusted. Also altered the procesbeheersplan P-BXT-NL-10116 cp 6.5 with the temperature measures before packing. | The staff is instructed to take the correct actions and this will also be recorded on the Ssop. The managers are instructed to plan only instructed staff on these positions. | The additional corrective action was not noticed during the validation of the adjusted cooling and way of working, 5 years ago. | 2020-07-27 | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | chilling process need to be controlled; the corrective actions towards the production since the previous measurement isn't described. | Training records of the staff and adjusted documents are seen.<br><br>Minor is fully closed. | | | | |
| 02 | 3.3.2. | The registration documents of the label checks in the packaging departments are stored for 1 week. This isn't in conformity with the BRC requirement of shelf life + 1 year. | Since the last audit day the registration documents are kept and stored.<br><br>The adjusted procedure and photo of the current storage of registration documents are seen.<br><br>Minor is fully closed | Procedure Databeheer P-BXT-NL-10234 adjusted with BB + 1 Year. A digital storage in is prepared and the departments will be instructed to store the documents in . | It was not clear to all departments what the storage time was of these documents | 2020-07-27 | |
| 03 | 4.4.1. | The wall of the equalization chilled storage cell is damaged at several places. | A quotation has been requested to an external company to repair the damage; the repair will be performed before 1-11-2020<br><br>Minor is closed and practical implementation will be verified next audit | A new floor cleaning cart is developed, which is constructed differently and cannot cause this damage, also the staff is instructed. | The old floor cleaning cart was not always used as instructed. They hit the wall at several places and caused the damage | 2020-07-27 | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 04 | 4.9.2.1. | The daily knife check is recorded at F-BXT-NL-10159 / control of knifes and gloves. Process is based at a registration at the begin and end of the production day. Records of the past 4 months are verified and the registration at the end of the day is missing at several days/weeks: week 30: Wednesday-Friday, week 28: Thursday/Friday, week 19: Monday – Friday | A correction is NA.<br><br>Training records of the instruction are seen. Practice will be verified next BRC audit.<br><br>Minor is closed | The concerning new knife sharpeners are reinstructed to fill out the forms completely. Also the new foreman is reinstructed to verify the forms also if they are filled out completely | The new knife sharpener and the new foreman where not instructed properly. | **2020-07-27** | |
| 05 | 4.9.3.2. | Glass audits are kept 4x/year. The results of glass audits kept in March 2020 in the Azie-packing and packaging department are seen; the follow up of the reported deviations isn't demonstrable. | An E-mail from the cutting room has therefore been been found, showing that the check has been carried out and reported to the technical service.<br><br>Minor is closed; practical implementation will be verified next audit | The print screens of these Emails will be digital stored, to demonstrate this in the future. Also the results of the audit will be stored digital. | The glass audits had been carried out, but the documents of some departments were in the mailbox of a colleague who worked from home, so they were not demonstrable. Also that these had been reported to the technical service. could not be proven | **2020-07-27** | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 06 | 4.11.8.1. | The EM programme is integrated in the yearly planning sampling and based at listeria sampling. The results of April 2020 of the EM programme are not available. | New samples were taken in week 33 2020.<br><br>Results sampling week 33 are seen.<br><br>Minor is closed and practical implementation will be verified next audit. | The results of the EM programme are added to the total overview of microbiological results and only then ticking off the schedule. With this process the realization of the EM program can be controlled | The planned sampling had not been carried out for various reasons and this wasn't noticed. | **2020-07-27** | |
| 07 | 4.14.9 | The overview of recommendations of the pest control agency show 1 outstanding recommendation dated 08.03.2019. This aspect was also reported with high priority in the yearly quality inspection dated 13.11.2019. | The follow up for this recommendation is planned for 01-10-20<br><br>Minor is closed and will be verified next audit. | The facility management department is informed to report recommendations related to maintenance must be reported in the maintenance management system for further action. | In this particular area, several replacements and repairs had to be carried out, which could damage the recommended actions. Therefor this was planned afterwards. But this wasn't communicated with facility management. | **2020-07-27** | |
| 08 | 6.4.2. | A fat analyser, type [redacted] is in use for the measurement of the fat content of 'mager met'. The equipment is listed at P-BXT-NL-10123 overview calibration | An external measurement is verified, and the result is compared this with the results of the own measurement. The results were similar. | The process is based at the comparison of the results of external measurements with the test results of Vion. The results will be recorded. | The external fat analysing was performed however there was no structural process to compare the results with the own test results and | **2020-07-27** | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | with a calibration frequency of 2x/year. There are no calibration results over 2019-2020 for the fat analyser. | Minor is fully closed | | recording this as a calibration step. | | |
| 09 | 7.1.2. | is taken care of the CCP1 checks in the slaughtering department. He's not demonstrable trained for this task. | 5-8-20 Mr was trained in CCP1 checks.<br><br>Training record is seen.<br><br>Minor is fully closed. | CCP training records are available in the training matrix. The supervisors/managers are instructed only to schedule demonstrable trained employees at control functions around CCP's. | trained by the department and fully aware of the procedure, but this training was not recorded. | **2020-07-27** | |
| 10 | 7.1.5. | Temporary workers and are working with system, used for labelling aspects. There are not demonstrable trained for this. | and and the rest of the staff which performs these tasks are being instructed and this is recorded.<br><br>Minor is closed and practical implementation will be verified next audit | A project will be started to create a process to link the work planning to a skill matrix. | The staff involved in working with the ystem and labelling check have been trained by training on the Job. However, the company wasn't aware of the fact that this must be recorded | **2020-07-27** | |

| Comments on non-conformities |
| --- |
| |

# Additional Modules / Head Office Non-Conformity Summary Sheet

| Critical | | | |
|---|---|---|---|
| No. | Requirement ref. | Details of non-conformity | Anticipated re-audit date |
| | | | |
| | | | |
| | | | |

| Major | | | | | | | |
|---|---|---|---|---|---|---|---|
| No. | Requirement ref. | Details of non-conformity | Corrective action taken | Proposed preventive action plan | Root cause analysis | Date reviewed | Reviewed by |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

| Minor | | | | | | | |
|---|---|---|---|---|---|---|---|
| No. | Requirement ref. | Details of non-conformity | Corrective action taken | Proposed preventive action plan | Root cause analysis | Date reviewed | Reviewed by |
| | | | | | | | |
| | | | | | | | |

## 1. Senior management commitment

### 1.1 Senior management commitment and continual improvement

The company is working with the VOS systematic of communication, measuring results and management of improvement. VOS is based at the lean management principles. The communication levels are described in P-BXT-10028 and is based at a cascading model, based at 2-4/day team huddles, daily tier 1 meeting and weekly tier 2 meetings. Objectives are documented in the X-matrix and are demonstrably linked to the vision and mission of the Vion group. There are 4 non-negotiable objectives for 2020: digital SSOP, complaint management/focus at operations, production scheduling with and integration Boxtel-Scherpenzeel (Boxtel fase 2). Other objectives are related to the food safety culture (training) and product flow management at shopfloor / WIP. Progress of the objectives is reported at a 4-weekly base during the tier 2 meeting.

Clearly defined Food safety and quality policy 2020 seen in which the intention of the site to produce and deliver safe, good, reliable and sustainable products is described; signed by the site manager at 08.01.2020.

The progress of realisation of objectives are monitored via the Q-based Q-report. (seen report Q2-2020). Reviewed aspects in the Q-report are animal welfare, EKS, complaints, food safety, suppliers, training. Yearly management review process covering the period July – June. The management review report July 2017 – June 2019, report date 09.08.2019 is seen; corrective actions are clearly defined and added to the X-matrix of the current year. Q-reports and management review are demonstrably discussed during tier 1 meetings.

Vion has a general whistle blower procedure for all employees, based at the possibility to report via telephone anonymous concerns. There have been no notifications in 2019 for Vion Boxtel.

The original audit was postponed due to Covid 19. There's a temporarily certificate based at a Covid 19 risk assessment performed at the 4th of June 2020. The BRCGS audit in 2021 will be scheduled before the original due date of 28.06.2021.

The company has an original BRCGS food document, the logo use is in conformity with the guidelines.

The organ chart is up-to-date and in line with the current organization. Job descriptions are reviewed. Performance is reviewed by day-to-day management and yearly during the POP/PPP reviews.

| 1.2 Organisational structure, responsibilities and management authority | |
|---|---|
| Details of non-applicable clauses with justification | |
| Clause/Section reference | Justification |
| | |
| | |

| 2 The Food Safety Plan – HACCP |
|---|
| The company's food safety control system is based on the Codex Alimentarius HACCP principles: an assessment is made of microbiological, chemical and physical risks for all steps in the production process, packaging material and general elements. The generic HACCP analyses of Vion is documented as P-FOOD-10000. The HACCP analysis is carried out by the group QA department of the Vion Group and the results are locally translated to the process control plan for the plant Vion Boxtel BV. In this way the site is informed and updated with legal, product & technology information. Additional assessments are performed for food defense (P-FOOD-10051) and food fraud (process integrity control plan P-NL-FOOD-10211). The local process control plan is documented as P-BXT-NL-100116. The site has 8 CCP's and 38 control points (CP's). |
| The QA manager is the food safety team leader; he is sufficient educated and well experienced. The Food safety team exist of the MT of the site. Quality and food safety are fixed agenda topics of the weekly tier 1 meetings. |
| The prerequisite programme is part of the QMS system and is based at EG 853 and EG 854 requirements. Verification by the daily pre-SSOP and SSOP checks.<br><br>Flow diagrams are seen and is verified for the process of removal of tenderloin and cutting of tails; no deviations found. Yearly review of flow diagrams; last review was 09.08.2019. |
| Different product groups are applicable (Procedure Products Boxtel P-BXT-NL-10.170):<br>• Fresh pork meat (Dutch origin);<br>• By-products (category 3);<br>• Destruction material (category 2);<br>• Partially chilled pork meat (50% / 70%) |

| |
|---|
| The intended use of the product by the customer has been clearly defined. No specific groups are applicable. The intended use is business to business pork meat and a few vacuumed consumer products (Greece) |
| The company has defined 8 Critical Control Points (CCP's):<br>1. Faecal contamination of carcasses (Zero tolerance for visible faecal contamination);<br>2. Temperature control of animal by-products at dispatch <= 3°C vacuum <=2 °C;<br>3. Temperature control of fresh / vacuum packed pork meat at dispatch <= 7°C vacuum <=6 °C, organs <2 °C);<br>4. Temperature control of partially chilled pork meat (6-hour transport) at dispatch, surface <= 7,0 °C<br>5. Temperature control of partially chilled pork meat (30 hours transport) at dispatch surface <= 7,0 °C, temperature <= 15,0 °C .<br>6. Temperature control of fresh pork meat at reception <= 7°C<br>7. Temperature control of returned animal by-products at reception <= 3°C;<br>8. Temperature control of returned fresh pork meat at reception <= 7°C.<br>Clear instructions about control procedures, critical limits and corrective measurements are seen.<br>There's a yearly verification of the HACCP system, the report of the last reassessment (09.08.2019) is seen.<br>Changes in process and products are validated by the food safety team. The last validation was done at the CCP 4/5 caused by changes in the legislation; report validation is seen.<br>1 minor NC is reported for this chapter; this is related to the temperature control of organs in relation to CP 31/32. |

**Details of non-applicable clauses with justification**

| Clause/section reference | Justification |
|---|---|
| | |
| | |

## 3. Food safety and quality management system

### 3.1 Food safety and quality manual

Vion Food is using a common digital system for the documentation related to the food safety and quality manual. This is managed by the central QA department. Each site has its own area within the system for local procedures and work instructions.

### 3.2 Document Control

An electronic quality manual named is in place. Changes are processes via a workflow system.

### 3.3 Record completion and maintenance

The following records are verified as part of the vertical test: SSOP's, pre-SSOP's, CCP checks, knife checks, label checks. This has resulted in 1 minor NC: the records of the labelchecks are stored for 1 week in stead of the defined period within Vion.

### 3.4 Internal audits

The internal audit plan 2020 is seen. 5 internal audits are scheduled throughout the year. The last internal audit report is kept 16.06.2020; 9 minor NC's are reported and follow up is demonstrably. Internal audit is kept by ; his qualification is based at a Lead assessor training (certificate 22.12.2015 is seen). Also the report of the internal audit with theme animal welfare, report dated 23.07.2020, is seen. Follow up is demonstrably.

Hygiene and fabrication inspections are kept at a daily base (pre-SSOP and SSOP checks). On top of that there's a quarterly based in depth inspection of the architectural aspects. The results are shared with the maintenance department.

### 3.5 Supplier and raw material approval and performance monitoring

#### 3.5.1 Management of suppliers of raw material and packaging

The management of suppliers is a corporate responsibility within the Vion Group.
Vion Farming is taken care for the suppliers of livestock (pigs and cattle) documented in P-NL-Food 10157 and verified for pork. canalisation GB delivered (trace test and during the audit) at 03.04.2020 UBN and UBN .These pig manures are demonstrably GB approved.

Purchasing processes of raw materials (ingredients) and packaging materials are centrally managed via approval procedures and contracts. The Vion plants are only authorised to order products or services from approved suppliers:

- Procedure supplier's audit (P-FOOD-10023);
- Procedure food supplier assessment' (P-FOOD-10025)
- Procedure requirements products and services (P-FOOD-10026).

There's an audit plan for external suppliers, based on risk management. Site Vion Boxtel BV has no external suppliers of pork meat, except incidental ham products from the Vion site in Apeldoorn (also BRC certificated).
There's a yearly assessment of suppliers; each Vion site is asked for input. Overview 2019 is seen: input from Vion Boxtel about 2 suppliers of packaging materials: and is seen.

| 3.5.2 Raw material and packaging acceptance, monitoring and management procedures |
|---|
| Livestock deliveries are checked at their requirements by an administrative check of the delivery documents before slaughtering. A veterinarian check at animal welfare and health aspects is carried out by the local veterinarian (employed by the Dutch government / nVWA).<br>Vion Boxtel BV is incidentally processing meat, delivered by the Vion plant in Apeldoorn (Dutch hams). The temperature of incoming meat is CCP6.<br>Packaging materials are inspected visual during delivery. |
| **3.5.3 Management of suppliers of services** |
| Purchasing processes of transport, storage and services are partly centrally managed via approval procedures and contracts and partly by the site for local deliveries.<br>The Vion plants are only authorised to order products or services from approved suppliers: Procedure requirements products and services' (P-FOOD-10026).<br>Yearly monitoring of suppliers is executed and seen from 12-2019. Is verified for suppliers of services ' I and ' no remarks. Assessment of suppliers of transport companies by transport audits: Audit report of transport company :, the result of the transport audit in February 2020 is seen; no remarks. |
| **3.5.4 Management of Out sourced processing** |
| No outsourced processing |

## 3.6 Specifications

Specifications are managed by the HQ department master data management.

The following specifications are sampled and verified during the audit

- Shoulder 4D Gyros
- [illegible] vacuum foil bottum
- [illegible] vacuum foil top
- Art [illegible] neck vacuum
- Art [illegible] shoulder 4D F
- Art [illegible] Robusto

Specifications were available in an up-to-date version. Review of specifications is at least 1 x / 3 years.

## 3.7 Corrective and preventive actions

Process of corrective and preventive actions is related to VOS for the operational processes. Corrective actions related to complaints are communicated via the tier 1 structure. Corrective actions related to pest control, pre SSOP, SSOP are recorded and demonstrable. In case of unfavourable trends an A3 improvement process is starting to investigate the root cause and identify measurements to improve. The current A3 process to improve the temperature control of organs is seen. This is based at a go-look-see investment of the current cooling process and identification of potential improvements. The presentation dated 02.07.2020 is seen about the update of the project.

## 3.8 Control of non-conforming product

Clear procedures for control of non-conforming products (e.g. fallen meat, blockades) are in place: P-BXT-NL10131. Products on hold are physically identified as such (red label/tape). Process is seen in practise during the site audit for at batch of hams, which were fallen at the ground and handled in conformity with the procedure. The procedure for non-conforming product defines how non-conforming product is identified, quarantined and disposed of. Only authorised personnel (QA Manager or department manager) are allowed to release products

## 3.9 Traceability

Traceability system is well developed. It covers raw materials through work in progress to finished product including packaging materials and distribution according to 'procedure traceerbaarheid' (P-P-Food-10015). This system is fully based on written documents, batch codes and bar codes, managed by .

- Porks bear an earmark (+ accompanied by track record and VKI)
- Half carcasses get an EG-mark + serial number (together with date of slaughter + slaughter line number + origin)
- Technical parts (own production + additional purchase) get a batch code (EG-mark + date of production + origin)
- By-products get a batch code (date of slaughter / production)
- Finished product is traced depending on the date of production + calculation number + serial number of EG-mark (weighing label is scanned at dispatch)
- Primary packaging materials are traced on the date of receipt / breaking into new batches
- Returned product + NAR (destination form)

Traceability tests including mass balance are kept at least 2x/year. The reports of the traceability tests of 21.07.2020 is seen.

During the audit a vertical test is kept for the product art shoulder 4D vacuum packed, produced for client [illegible], order produced at 06/07.04.2020; slaughterdate 03.04.2020.

The test was performed well within 3 hours, showing a sustainable system of tracking and tracing of product and corresponding documentation.
Documents showed during the test: End product specification, CCP training documents, Control on cleaning (Agar and residues), Trend analyse agar control, Distribution documents, Weight lists, Label check, Traceability to slaughter house number, specifications of packaging material, trace on packaging material, monthly trend micro results, SSOP checks, PRE SSOP, Verification list CCPs, Monitoring list CCPs, Pre-shipment control list, knife control checks. Trace for/backwards.
The production process has no rework flows.

## 3.10 Complaint handling

Complaints are received by the sales organisation and send to the complaint inbox email address of Vion Boxtel. Complaint handling is performed at a daily base within the prescribed timelines. Process is verified for complaint [redacted]: metal at shoulder. Good organised process with in depth analyses for food safety complaints and link to the VOS system. There's a weekly complaint analysis report for the MT, which is discussed in the tier 1 meetings. The trend is upwards for complaints in 2019. This is related to complaints about high temperature of tongues. This has resulted in a A3/go-look-see action for the chilling process; see chapter 3.7.

## 3.11 Management of incidents, product withdrawal and product recall

There is a Vion overall crisis and recall management procedure P-VION-10015 which covers the process which is applicable for all Vion sites. The procedure for non-conforming product defines 'incidents' and addresses requirements in terms of incident reporting as these are escalated to relevant personnel for review and action as appropriate. Business continuity guaranteed by central procedures and emergency coordination protocol. The local procedure Product recall P-BXT-NL-10024 defines the composition of the recall team and complies with these requirements.
The recall procedure is tested 1x / year. Last mock up recall was 21-07-2020; report is verified; no remarks. No recalls since last BRC audit. There was 1 withdrawal related to wrong labelling of a batch.

## Details of non-applicable clauses with justification

| Clause/section reference | Justification |
|---|---|
| 3.5.4. | No outsourced processing |
| | |

## 4. Site standards

### 4.1 External standards

Site is located in Boxtel, which is in the south of the Netherlands. At the same address the meat processing plant of Vion is located. At the opposite of the street the HQ of the Vion Food group is located and a new storage location for packaging materials and technical components for all dutch Vion sites.
Site boundaries are clearly marked and fenced. Separate storage takes place for cleaning chemicals, lubricants and waste. The site is registered by The Food and Consumer Product Safety Authority (official approval EG 61). At the moment building works are in process related to the project to extent the site in Boxtel with the processing of middles.

### 4.2 Site security and food defence

24h/7 site security during production days from 06:00 till 22:00 by own trained staff the rest is covered by . There is a system in place with badge control for employees and identification and badge control for visitors and contractors on all potential entry points to the plant. Reassessment Food defence executed 09-08-2019 including verification of the food defence plan. Actual site diagrams are seen

### 4.3 Layout, product flow and segregation

The slaughtering, processing and packaging areas of the production are well designed and maintained to prevent risk of contamination. Premises are suitable for the intended purpose. Process flow is designed to minimise/prevent contamination and agreed with the Food and Consumer Product Safety Authority. Personnel-, material-, air-, water, waste-, services flows are designed and equipment placed in such a manner as to minimise the risk of product contamination.
No high risk or high care production assigned on site. In the low-risk areas, effective procedures are in place to minimise the risk of the contamination.
Actual site map dated 12.12.2018 is seen and contains the flows as described in 4.3.1

### 4.4 Building fabric, raw material handling, preparation, processing, packing and storage areas

The internal condition of the site is suitable and satisfactory for the process. Walls, ceilings and floors were suitable in general. Floors are coated or granite and in good condition. Continuous attention is given to the condition of the floors. This was verified for the floor in the Asia packaging department. The repair of this floor is known within and will be scheduled during the next "floor repair" saturday. False ceilings are in place in manufacturing area, which are full closed. In case of glass windows, these are protected by foil. Suitable ventilation and cooling throughout the factory.

Daily check of the condition by the SSOP checks and in depth by the quarterly inspection of fabrication and hygiene aspects.

1 minor NC is reported for this chapter: the wall of the equalization chilled area is seriously damaged.

### 4.5 Utilities - water, ice, air and other gases

The water used for cleaning and process purposes is water from the main supply. Testing of water (chemical/microbiological) is part of the microbiological monitoring plan P-BXT-NL-10009 and P-NL-Food-10.196C. The samples are analysed by which is an ISO 17025 accredited laboratory . Water quality is defined as a CP. Sampling frequency is 4 times a year, last tests assessed from 09.12.2019, 18.12.2019 (legionella) and 17.03.2020, all results were within the standard.

Due to the sensitivity of cold areas in slaughterhouses for Covid 19 a fogging protocol is in use for the reduction of virus activity in aerosols. This is based at MSDS information is seen.

## 4.6 Equipment

Equipment was suitably designed and used to minimise potential contamination. The used equipment is suitable for its purpose. New equipment is purchased as required and specified.

## 4.7 Maintenance

The process equipment and main process steps are monitored by the maintenance department via a in combination with camera surveillance at vital points of the installation. Systems are generating SMS messages to mechanics in case of failures and deviations. In 2020 the maintenance system is changed into . New machines are directly incorporated in the . Process is verified for the chopper installation in the slaughtering line (maintenance report 19.05.2020 is seen), the shooting mask 26090 (last control performed at 02.07.2020) and rind removal equipment nr 9 (revision report 02.03.2020). Maintenance and activities for disturbances/failures are typically and preferably planned and carried out after production hours or in the weekend. Release of equipment after repairs and/or maintenance are signed off via the (pre)SSOP forms. Repairs/maintenance are communicated with team leaders and other relevant people, as well as the cleaning company, to keep focus on hygiene.

All used lubricants are food grade with a FDA H1 status (food grade). Automatic lubricant system in use for the main process like transport chains.

Maintenance people are trained on hygiene and contamination prevention. A sole washer is present at the entrance of the clean slaughtering department. Main Maintenance Department is located in a separated building from the production.

## 4.8 Staff facilities

Canteen and changing rooms (production and dirty slaughter house) were assessed. Facilities are designed to a good level. Cleaning and maintenance are in good order, to prevent contamination or food safety risks. Outdoor clothing and shoes are stored separately from work wear.

In the staff facilities areas dedicated routes based at 1-way traffic is organised to maintain the social distance of 1.5 meter (covid 19 protocol).

Hand-washing facilities (with hand-free soap tap operation and air blade dryer / single use paper towels) were provided in toilets and at entry points to production areas. Before entering the production areas boot washing and hand disinfecting equipment is installed including a tourniquet.

Rest room and catering facilities are provided for staff. A HACCP plan is applicable. Smoking is only allowed in a separated area of the canteen. No evidence of smoking was seen during the site evaluation. Proper storage areas and fridge were observed for brought food stuffs.

## 4.9 Chemical and physical product contamination control: raw material handling, preparation, processing, packing and storage areas

| 4.9.1 Chemical control |
|---|
| Chemicals/cleaning agents are stored separately and away from production. Authorised access by cleaning company and production department. MSDS available and specifications confirm suitability for use in food processing industries. This is verified for (floor cleaner) and (used during fogging). Both MSDS documents are seen and the used dosages are in conformity with the prescribed dosages. |
| 4.9.2 Metal control |
| The HACCP study has determined that metal detection is not necessary as CCP, but as CP. Registration and corrective actions could be demonstrated. A knife handling policy is in place.<br><br>A minor NC is reported for this chapter: the systematic of recording knife check records isn't closing. |
| 4.9.3 Glass, brittle plastic, ceramics and similar materials |
| A glass / hard plastic register is in place and records the location and condition of glass / hard plastic. Glass / hard plastic audits are regularly carried out by production department (daily pre-SSOP and SSOP). Besides daily check, 1 x / 3 months audits are executed by the verification of the glass register, which is documented as a map of the specific department. Verified for the glass audit in March 2020 for the Asian packing department and meat packing department. Both reports were seen, but the follow up of deviations found isn't demonstrable. This has resulted in a minor NC. |
| 4.9.4 Products packed into glass or other brittle containers |
| No products packed into glass or other brittle containers |
| 4.9.5 Wood |
| Wooden pallets are not permitted in production of pork meat (only non-food area; storage of packing materials). |
| 4.9.6 Other physical contaminants |
| Only the use of metal detectable pens is allowed. |
| 4.10 Foreign body detection and removal equipment |
| 4.10.1 Selection and operation of foreign body detection and removal equipment |
| The HACCP study determined the metal detection step as a CP, not a CCP. Checks are performed every hour. Employees for monitoring are trained by an instruction. During the audit the use and control of the metal detection equipment was assessed at the packing area (vacuum products). Method and recording in line with the procedures. Training records of and are verified and up-to-date. |
| 4.10.2 Filters and sieves |
| Sieves and filters are not in use for product checks. |

| 4.10.3 Metal detectors and X-ray equipment |
|---|
| Metal detection devices are used to check for unpacked products, tongues and vacuum-packed products. Appropriate foreign body detection equipment (metal detectors) is in place, calibration of equipment is demonstrable. Metal detector check is performed correctly, as well as registration of results and, in case of non-conformance, corrective measures. Used test pieces are 4.0 mm Fe, 5.0 mm non-Fe and 8.0 mm SS. |
| 4.10.4 Magnets |
| Magnets are not in use |
| 4.10.5 Optical sorting equipment |
| No use op optical sorting equipment |
| 4.10.6 Container cleanliness – glass jars, cans and other rigid containers |
| No glass jars, cans and other rigid containers in use |
| 4.11 Housekeeping and hygiene |
| Cleaning is subcontracted and performed by in the evening/ at night after production. Cleaning of equipment is carried out according to documented and detailed cleaning schedules.<br><br>Specific or dedicated equipment, such as whizard knifes and balances are cleaned by own employees. Also the chilled storage areas are cleaned by own employees, working at the facility management department.<br><br>The effectiveness of the cleaning and disinfection process is followed by hygiene audits (pre-SSOP), agars and swabs for pathogens (e.g. Listeria). Records of checks are maintained and were sampled during the audit, both of as the pre-SSOP lists. Cleaning schedules of are available and cover equipment, plant, buildings and services (with daily / weekly / monthly cleaning frequencies). Low frequent cleaning schedule (ceilings, walls above 2,5m, evaporators) are scheduled via the overview of periodic cleaning tasks. Is verified for the periodic cleaning of buffer cell 5 (chilled area) and ceiling of the 'veredeling' department and records were demonstrably. Pre-SSOP registrations are carried out correctly, deviations from schedule are followed up properly.<br><br>Employees using cleaning chemicals are trained by the supplier; training records of dated 03.01.2019 are seen.<br><br>Specifications of the cleaning agents delivered by (consisting of MSDS and food grade certificate) are present eg. |
| 4.11.7 Cleaning in place (CIP) |
| A cleaning in place system is used for the cleaning of the blood vessels and tank and the cleaning of knifes and crates. Temperature is monitored in CIP process blood vessels is verified with agar sampling. Results 2020 are seen and are all low. |
| 4.11.8 Environmental monitoring |

Environmental monitoring is based at Listeria swabs with a frequency of 4x/year. Results of 2019 – 2020 are verified. The results of the last swab round in April 2020 are not demonstrable, this has resulted in a minor NC.

## 4.12 Waste

The site has several types of waste materials. The removal of waste is done by contracted and licensed waste removal companies.

Cat 2/3 is removed by and Other types of waste are paper, carton, plastic, metal, wood, chemicals and residual waste. Company is contracted for the removal of these types of wastes.

## 4.13 Management of surplus food and products for animal feed

All waste material based at pork is unpacked before removal. No waste material for animal feed products

## 4.14 Pest management

Pest control is outsourced to a contracted pest control agency . Contract management by Vion HQ. Contract is covering the pest control of rodents, insects and mots. Control frequency 8x/year and a yearly in-depth inspection.

Competences of pestcontrol inspector is verified (EVM recognised until 14-12-2022) and (EVM recognised until 13-04-2022).

The technical area for the mildchill is verified at the site diagram. It's clear that there's no possibility for rodents/insects to come in to this area, so it is justified that no pest control measurements are there. . Report of the inspections at 19.09.2019 and 29.10.2019 is seen.

Measures for bird protection by the use of bird pens.

Follow up of recommendations of the pest control agency isn't timely; there's 1 outstanding recommendation since 08.03.2019. This has resulted in a minor NC.

The in-depth inspection was kept at 13.11.2019; follow up actions is finalised.

The trend analysis of the pest control activities is part of the reassessment process. Stable trend, low activity of rodents and insects.

## 4.15 Storage facilities

The company is producing fresh pork meat. Carcasses are stored 1-3 days before they are cut to specification. Storage temperatures are controlled automatically via the Used temperature standards are in conformity with the legislative demands about temperature.
Production and expedition processes are organised based at the FIFO principle. Part of the production output is distributed to contracted frozen storage locations.

| 4.16 Dispatch and transport |
|---|
| Temperature during dispatch of the product is a CCP. Records of the CCP check and the preshipment process were verified during the audit and as a part of the vertical test. (6-8 April 2020) Transport is organised and scheduled by the Service desk. They are only scheduling approved transport companies. Trucks are inspected for hygiene and temperature prior to loading. Results of these inspections are recorded on the CCP control forms F-BXT-NL-10045. There's a schedule for audits of the transport companies and a verification of the cleaning by agar samples, see chapter 5.4.3 |

**Details of non-applicable clauses with justification**

| Clause/section reference | Justification |
|---|---|
| 4.9.1.2. | No strongly scented or taint-forming materials in use |
| 4.9.4. | No products packed into glass or other brittle containers |
| 4.10.2. | No filters or sieves in the process of this company |
| 4.10.4 | No magnets in use |
| 4.10.5 | No optical sorting equipment |
| 4.10.6. | No container cleanliness-glass jars, cans or other rigid containers in use |
| 4.13 | No surplus food and products for animal feed in this company |

## 5. Product control

| 5.1 Product design/development |
|---|
| The product development process is centrally organised within the Vion Food. There are no product development activities at the Boxtel site (changes are mostly changes in snit). New processes are validated before implementation. The validation of the new middles processing department in Boxtel is already started. |

Shelf life / best before date trials are coordinated by the central QA department of Vion Food, except for shelf life trials on customer demand. Shelf life trial samples are taken in conformance of the central shelf life trial plan and seen during the audit, for different temperatures and shelf life (stored at 0-2 and 4 degrees). The current used shelf life terms are in line with the shelf life test results

### 5.2 Product labelling

Bulk products are delivered with product specifications based on customer requirements and legislation aspects. Labelling text is based at product description, production date, shelf life term, country of origin and storage conditions. There are 2 vacuum packed consumer products. Ingredients are mentioned at the labelling text. Label Shoulder 4D vacuum (vertical test) verified: no remarks.

### 5.3 Management of allergens

No allergens on site under current scope, only production and handling of fresh meat.
The risk of allergens via employees / food stuff is part of the risk assessment. This is controlled with the following measurements: it's not allowed to wear the work coat in the canteen and all employees need to wash and disinfect their hands before they are entering the production facilities and the wearing of gloves. Allergen management is part of the refresher training for employees and introduction training for new starters.

### 5.4 Product authenticity, claims and chain of custody

The vulnerability assessment is documented as Process integrity control plan P-NL-FOOD-10049, reviewed at 26.05.2020. Aspects like replacements and substitution are part of the vulnerability assessment. The company is recently certificated for IFS PIA. A daily mass balance is one of the requirements of the scheme.
Organisation is certified for: QS, IKB, Better life 1*, and IFS PIA

### 5.5 Product packaging

The packaging and supplier approval are managed by the central purchase department at Vion Food HQ. There's a list of approved suppliers of primary packaging materials. Primary packaging materials are appropriate for the intended use. This is verified for the trays and all relevant documents (specification, food grade statement, migration tests) were available. Product packaging material is checked against visual standards of acceptability upon arrival at the site. There is a separated storage area for primary packaging materials.

### 5.6 Product inspection and laboratory testing

#### 5.6.1 Product inspection and testing

Livestock/pigs are controlled by a veterinarian during the arrival at the slaughter department and during the process in the clean slaughter line (control for diseases intestinal check).

All analyses (hygienograms, microbiology, pathogens, shelf life water, etc.) are subcontracted to an accredited laboratory operating in accordance with ISO 17025:
). A microbiological monitoring program 'procedure planning monstername 2020 / P-BXT-NL-10011 and shelf life testing program 'Houdbaarheidsonderzoeken' (P-FOOD-10010 and P-NLFOOD-10165) are in place and were assessed.

The frequency of monitoring depends on the risk:
Carcasses own production: daily microbiological analysis of TPC, entero's, (pool) Salmonella (process hygiene);
Trimmings: daily microbiological analysis of TPC, entero's, (pool) Salmonella and listeria;
Deboned meat: 1 x / week microbiological analysis of TPC, entero's, Salmonella and Listeria;
Technical cuts, by-products and organs: 1 x / 2 weeks microbiological analysis of TPC, entero's, Salmonella and Listeria.

**5.6.2 Laboratory testing**

Results of TPC and pathogens (every thousand carcass) are analysed and reported monthly (KPI reporting). Trend graphs are applied. Results are analysed at trends at a monthly base (Q report). Tests are assessed for raw materials and finished goods..
Results of the monitoring programme are part of the quarterly based review of the food safety and quality system. Results are verified: stable trend for PCA, Salmonella has some positive results, no need for further action, because of the full cooking step in the chain (VO 2072:2005); no listeria found.

**5.7 Product release**

Products are released after the pre-shipment controls, which are carried out by the expedition department. The verification of CCP controls is part of the pre-shipment process. Verification procedure and checklists were assessed during the audit at dispatch and during the vertical audit (07/08 April 2020) (F-BXT-NL-10048).

**5.8 Pet Food**

No production of pet food.

**Details of non-applicable clauses with justification**

| Clause/section reference | Justification |
|---|---|
| 5.3; except 5.3.3. | No allergens |
| 5.8 | No production of pet food |
| | |

## 6. Process control

### 6.1 Control of operations

Process conditions and methods are well monitored and re-validated when necessary. In case of breakdown of critical equipment, a system and procedure are in place for the proper handling of product. Verification of process and equipment takes place once a year. The results are used and discussed as input in the yearly management review. QA monitors aspect of the controls that might affect food safety, legal and quality characteristics. The control of operations is partly at visual inspection during the process by operators and supervisors. Checks are made at the SSOP forms for process controls, such as temperatures.
Via a camera system and the there's a real time overview at the control of operations. Special attention for animal welfare aspects with camera supervision.
The cooling system is linked to the In case of failures in the system an alarm system is in use. The temperature in the chilled storage area and storage expedition is verified for 7/8 April 2020 (vertical test). Temperature was < 2 C.
Daily meetings between management of the slaughtering department and maintenance department about break downs. This approach has reduced the level of breakdowns in the slaughtering department. This process will also being implemented for the cutting department.

### 6.2 Labelling and pack control

Label checks are taken place at the start and end of production batch. During the site audit in the cutting department the product change is monitored from ham with paw to ham without paw. Labels were changed via the system Label check of 1st label was seen. No need for change of packaging

### 6.3 Quantity, weight, volume and number control

All products are sold by weight. Weighing scales are in place and subjected to calibration and maintenance programme. Calibration reports of floor balance sian production) is seen; is calibrated at 14.03.2020'; also seen check balance hams 2.2/A152723: calibrated at 16.02.2020.

### 6.4 Calibration and control of measuring and monitoring devices

Critical measuring equipment are thermometers (CCP related), weighing scales, fat analyzer and metal detection equipment. These are calibrated. Records were available.
The equipment used to measure on CCP's is identified. List of measuring devices in place. Calibration due date on equipment. Seen calibration of thermometer 101 and 102, 2-monthly calibration records 2020 are seen.
The reports of half yearly calibration of the fat analyser were not available for 2019/2020, this has resulted in a minor NC.

### Details of non-applicable clauses with justification

| Clause/section reference | Justification |
|---|---|

| | |
|---|---|
| | |

## 7. Personnel

### 7.1 Training: raw material handling, preparation, processing, packing and storage areas

There's an introduction training for new employees including temporary workers. Employees engaged in the control of CCP's are trained regularly. Employees working in the dirty slaughtering department and stable get a dedicated training about animal welfare aspects.
The following training records are verified:

- , introduction training at 14.07.2020
- introduction training at 20.02.2020
- HACCP training supervisor at 14.06.2017
- CCP 1 training: no record could be found
- and : training in labelling process: no record could be found.
- 2 minor NC's are reported for this chapter related to the missing training records.

Competence review is part of the yearly POP process and reassessment / management review.

### 7.2 Personal hygiene: raw material handling, preparation, processing, packing and storage areas

The standards for personal hygiene are documented in the QMS as P-FOOD-10017; version 18/5/2020. The document is covering the requirements of the BRC 8 standard. The wearing of any jewellery isn't allowed.
Effectiveness of the hygiene procedures for personnel is part of the SSOP systematic.
A sample of each batch metal detectable plasters is demonstrable tested.

### 7.3 Medical screening

The medical screening is part of the intake of new employees and part of the instructions to visitors. The site makes all visitors, new starters and contractors aware of the need to report infectious disease during the intake by the porter before entering the site. In case of a disease the company is consulting a specialised company doctor. Persons who are suffering from relevant infectious diseases are not allowed to enter the production facilities. As a part of the covid 19 protocol each employee has to pass the triage process before entering the site before start working. In case of doubt the HSES doctor can decide to send them for a Corona test.

### 7.4 Protective clothing: employees or visitors to production areas

Protective company clothing is facilitated to all staff, temporary workers and visitors and changed daily. Workers are divided per rank and agency by different colour hair nets. The standards for personal hygiene, dress code, medicines, jewellery and medical screening have been defined (P-FOOD-10017). These hygiene rules are effectively enforced and daily inspected as a part of the SSOP control.

Protective clothes are provided in sufficient numbers. The laundering of protective clothing is outsourced to a contracted and specialised laundry ¡certification includes biocontamination control system and washing programs are verified).

The wearing of sleeves, aprons and work coats isn't allowed during eating and smoking. Disposable hair nets are in use; beard snoods are in use. Cleaning facilities are provided. Work shoes or boots needs to be worn, facilities to clean the soles are available in the hygiene corridors at the entrance of the production facilities. As a result of the Covid 19 protocol face masks are worn in the "cold areas: cutting lines, veredeling, packing areas and expedition.

| Details of non-applicable clauses with justification | |
|---|---|
| **Clause/section reference** | **Justification** |
| | |
| | |

## 8. High-Risk, High-Care and Ambient High-Care Production Risk Zones

### 8.1 Layout product flow and segregation in high-risk, high-care and ambient high-care zones

No high risk, high care or ambient high care production risk zone

### 8.2 Building fabric in high-risk and high-care zones

No high risk, high care or ambient high care production risk zone

### 8.3 Maintenance in high-risk and high-care zones

No high risk, high care or ambient high care production risk zone

### 8.4 Staff facilities for high-risk and high-care zones

No high risk, high care or ambient high care production risk zone

### 8.5 Housekeeping and hygiene in the high-risk high-care zones

| |
|---|
| No high risk, high care or ambient high care production risk zone |
| 8.6 Waste/Waste disposal in high risk, high care zones |
| No high risk, high care or ambient high care production risk zone |
| 8.7 Protective clothing in the high risk high care zones |
| No high risk, high care or ambient high care production risk zone |

| Details of non-applicable clauses with justification | |
|---|---|
| **Clause/section reference** | **Justification** |
| 8.1-8.7 | No high risk, high care or ambient high care production risk zone |
| | |

| 9 - Traded Products |
| --- |
| 9.1 Approval and performance monitoring of manufacturers/packers of traded food products |
| |
| 9.2 Specifications |
| |
| 9.3 Product inspection and laboratory testing |
| |
| 9.4 Product legality |
| |
| 9.5 Traceability |
| |

| Module 11: Meat supply chain assurance | |
| --- | --- |
| Scope | |
| 11.1 Traceability | |
| | |

| 11.2 Approval of meat supply chain |
| --- |
| |
| 11.3 Raw material receipt and inspection |
| |
| 11.4 Management of cross-contamination between species |
| |
| 11.5 Product testing |
| |
| 11.6 Training |
| |

## Module 12: AOECS Gluten-free Foods

| Scope | |
|---|---|
| 12.1 Senior management | |
| | |
| 12.2 Management of suppliers of raw materials and packaging | |
| | |
| 12.3 Outsourced production | |
| | |
| 12.4 Specifications | |
| | |
| 12.5 Management of gluten cross-contamination | |
| | |
| 12.6 Management of incidents, product withdrawal and product recall | |
| | |

| 12.7 Labelling |
| --- |
| |

| 12.8 Product inspection and laboratory testing |
| --- |
| |

| Module 13 FSMA Preventive Controls Preparedness Module<br>Version 2 July 2018 | | | | |
| --- | --- | --- | --- | --- |
| Item no. | Clause | Module item | Conforms (Y/N) or Not Applicable (N/A) | Comments |
| 1 | 13.1.1 | Handwashing areas, dressing and locker rooms, and toilet rooms must have adequate lighting. | | |
| 2 | 13.1.2 | Water distribution system must prevent backflow from, or cross-connection between, piping systems that discharge waste water or sewage. | | |
| 3 | 13.1.3 | All food contact surfaces of plant equipment and utensils used in manufacturing, processing, packing, or holding food must be corrosion resistant. | | |

| | | | | |
|---|---|---|---|---|
| | | Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact. | | |
| 4 | 13.1.4 | Ice used in contact with food must be manufactured in accordance with Good Manufacturing Practice (GMP) requirements of 21 CFR 117. | | |
| 5 | 13.1.5 | Where defect action levels (DAL) are established for a food, quality control operations must reduce defects to the lowest level possible.<br><br>Defect levels rendering the food adulterated may not be reduced by mixing the food with another lot. | | |
| 6 | 13.1.6 | The hazard analysis must additionally identify and evaluate the following known or reasonably foreseeable hazards, which are associated with the food or facility:<br>• Economic adulterants which affect food safety<br>• Environmental pathogens where ready-to-eat (RTE) food is exposed to the environment prior to packaging and the packaged food does not receive a kill step<br>• Radiological hazards<br>• Unintentional adulterants which affect food safety | | |
| 7 | 13.1.7 | All identified known or reasonably foreseeable hazards must be evaluated to determine "hazards requiring a preventive control" (i.e., significant hazards). | | |

| | | | | |
|---|---|---|---|---|
| 8 | 13.1.8 | Establish one or more preventive control(s) for each identified "hazard requiring a preventive control" (i.e., significant hazard) such that the control significantly minimizes or prevents the food manufactured, processed, packed, or held by the facility from being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug and Cosmetic Act. | | |
| 9 | 13.1.9 | Evaluate and update the recall and withdrawal procedure as necessary to ensure it contains procedures and responsibility for the following:<br>• Notifying consignees of how to return or dispose of recalled product<br>• Conducting effectiveness checks to verify recall is carried out<br>• Appropriate disposal (i.e., destroy, divert, repurpose) of recalled product | | |
| 10 | 13.1.10 | Establish monitoring activities and a written procedure for each preventive control consistent with the requirements of BRC section 2.10. | | |
| 11 | 13.1.11 | Establish corrective action procedures when preventive controls are not implemented consistent with the requirements of BRC sections 2.11 and 3.7.<br><br>Corrective action procedures must be established and implemented when the presence of a pathogen (or indicator organism) is detected as a part of verification activities (i.e., product testing and/or environmental monitoring). | | |

| | | | | |
|---|---|---|---|---|
| 12 | 13.1.12 | Validate all established process controls prior to implementation of the food safety plan, upon changes requiring re-validation or within 90 calendar days of the first food production.<br><br>Validate allergen, sanitation and supply-chain controls as appropriate to the nature of the hazard, control and facility. | | |
| 13 | 13.1.13 | The PCQI (or authorized designee) reviews monitoring and corrective action records within 7 days. Where an alternate timeframe exceeding 7 days is used, the PCQI must document justification.<br><br>The PCQI (or authorized designee) reviews verification records for all preventive controls (e.g., calibration records, product testing, supply-chain audits) within a reasonable timeframe after the record is created. | | |
| 14 | 13.1.14 | Where product testing for a pathogen (or indicator organism) or other hazard is used as a verification activity, a scientifically valid and written testing procedure must identify the following:<br>• Sampling procedure to include method, quantity, frequency, and number of samples<br>• Analytical method<br>• Laboratory conducting analysis<br>• Corrective action procedure where pathogen is detected | | |
| 15 | 13.1.15 | Where environmental monitoring for a pathogen (or indicator organism) is used as a verification activity, a scientifically valid and written testing procedure must identify the following: | | |

| | | | | |
|---|---|---|---|---|
| | | • Adequate number and location of sample sites<br>• Timing and frequency of sampling<br>• Analytical method<br>• Laboratory conducting analysis<br>• Corrective action procedure where pathogen is detected | | |
| 16 | 13.1.16 | Devices used to verify preventive controls must be calibrated. | | |
| 17 | 13.1.17 | Identify a Preventive Controls Qualified Individual (PCQI) responsible for developing the food safety plan, validating preventing controls, review of records, and reanalysis of the plan.<br><br>Document the PCQI's training and qualification via job experience. | | |
| 18 | 13.1.18 | All records required by 21 CFR § 117 must include:<br>• Date and time of activity being documented<br>• Signature/ initials of individual performing activity or conducting record review<br>• Information to identify the facility (e.g., name and location)<br>• Identity of the product and lot code where applicable | | |
| 19 | 13.1.19 | The owner, operator or agent in charge of facility must sign and date the written food safety plan initially and then upon any changes following reanalysis. | | |
| 20 | 13.1.20 | All documents and records relating to the food safety plan (i.e., all records required by 21 CFR § 117) must be retained at the facility for 2 years after the record is created. | | |

| | | | | |
|---|---|---|---|---|
| | | Where records are stored offsite, they must be retrievable within 24 hours with the exception of the food safety plan, which must remain onsite. | | |
| 21 | 13.1.21 | Where a hazard requiring a supply-chain-applied control is identified in the hazard analysis, the receiving facility must establish and implement specific supplier approval and verification activities.<br><br>Where a hazard requiring a supply-chain-applied control is identified AND the control is applied by an entity other than the receiving facility's supplier, the receiving facility is responsible for verifying implementation of the control. | | |
| 22 | 13.1.22 | Supplier approval must be documented before receiving and using raw materials and ingredients.<br><br>Verification activities must be conducted before receiving and using raw materials and ingredients on a temporary basis from unapproved suppliers. | | |
| 23 | 13.1.23 | One or more supplier verification activities (defined in § 117.410(b)) must be conducted for each supplier before using raw materials and ingredients AND periodically thereafter at an adequate frequency. | | |
| 24 | 13.2.1 | Human food by-products held for distribution as animal food must be held under conditions that will protect against contamination, including the following:<br><br>- During holding, human food by-products for use as animal food must be accurately identified.<br><br>* Labeling that identifies the product by the common or usual | | |

| | | | | |
|---|---|---|---|---|
| | | name must be affixed to or accompany the human food by-products for use as animal food when distributed.<br><br>* Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against the contamination of animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food. | | |
| 25 | 13.3.1 | A Qualified Individual (QI) is responsible for developing the site's food defense plan, conducting a vulnerability assessment, identifying mitigation strategies, and conducting a reanalysis of the plan. The QI responsible for developing the food defense plan shall be identified on the site's organizational chart.<br><br>One or more QI's shall be responsible for implementing mitigation strategies at actionable process steps. | | |
| 26 | 13.3.2 | The site shall have a written food defense plan, which includes the following:<br>• A vulnerability assessment identifying significant vulnerabilities and actionable process steps<br>• Mitigation strategies appropriate to reduce the vulnerability<br>• Procedures for food defense monitoring, | | |

| | | | | |
|---|---|---|---|---|
| | | corrective action and verification | | |
| 27 | 13.3.3 | A written vulnerability assessment shall be prepared for each food type manufactured, processed, packed, or held, which evaluates the following key criteria (at a minimum):<br>• Scale and severity of threat if a contaminant is added to product<br>• Degree of physical access to the product<br>• Ability of an attacker to successfully contaminate product—including consideration of an inside attacker<br>A vulnerability assessment shall be documented for each food type regardless of the outcome and provide justification as to why each point, step or procedure in the operation was or was not identified as an actionable process step. | | |
| 28 | 13.3.4 | Written mitigation strategies shall be established and implemented for each actionable process step identified in the vulnerability assessment.<br>Justification shall be documented explaining how the strategy significantly minimizes or prevents the vulnerability. | | |
| 29 | 13.3.5 | Written monitoring procedures shall be established and implemented to include the activity and frequency for monitoring food defense mitigation strategies.<br>Procedures shall include recordkeeping requirements for all monitoring activities. | | |

| | | | | |
|---|---|---|---|---|
| 30 | 13.3.6 | Written corrective action procedures shall be established and implemented when mitigation strategies are not properly implemented. The procedure shall include the following criteria:<br>• Method for identifying and correcting a lack of implementation<br>• Method for reducing the likelihood of recurrence<br>• Recordkeeping requirements for corrective actions | | |
| 31 | 13.3.7 | Written verification procedures shall be established and implemented to ensure that food defense monitoring and corrective action are performed according to procedures. Verification procedures shall describe activities to verify implementation of mitigation strategies.<br><br>Verification procedures shall include:<br>• A review of monitoring and corrective action records within an appropriate timeframe (e.g., 7 days)<br>• Other verification activities as appropriate (e.g., internal audit)<br>• Method for verifying that reanalysis of the food defense plan was conducted<br>• Frequency for verification activities<br>• Recordkeeping requirements of all verification activities | | |
| 32 | 13.3.8 | Reanalysis of the food defense plan shall be documented and performed every three years or whenever | | |

| | | | | |
|---|---|---|---|---|
| | | • A change in facility operations which creates a new significant vulnerability<br>• Knowledge about a new threat applicable to the food or facility becomes known<br>• Mitigation strategies are not implemented as intended<br>• FDA requires reanalysis based on new threats or scientific evidence | | |
| 33 | 13.3.9 | All records required by 21 CFR § 121 must include:<br>• Date and time of activity being documented<br>• Signature/ initials of individual performing activity or conducting record review<br>• Information to identify the facility (e.g., name and location)<br>• Identity of the product and lot code where applicable | | |
| 34 | 13.3.10 | The owner, operator or agent in charge of facility must sign and date the written food defense plan initially and then upon any changes following reanalysis. | | |
| 35 | 13.3.11 | All documents and records relating to the food defense plan (i.e., all records required by 21 CFR § 121) must be retained at the facility for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours with the exception of the food defense plan, which must remain onsite. | | |
| 36 | 13.4.1 | Vehicles and transportation equipment must be maintained and stored in a sanitary condition appropriate for the intended use to prevent food from becoming unsafe | | |

| | | | | |
|---|---|---|---|---|
| | | during transportation. Where inspection reveals that vehicles or containers are not in a clean condition, they shall not be used.<br><br>A documented procedure shall describe cleaning and storage practices of all vehicles and transportation equipment maintained by the site whether leased or owned and as appropriate for the intended use. The procedures shall be fully implemented. Cleaning activities shall be recorded. | | |
| 37 | 13.4.2 | The site shall ensure that contracts with U.S. shippers, receivers, loaders, and carriers specify their responsibility for compliance with FSMA's Sanitary Transportation rule. Where the site acts as the shipper or receiver, it shall ensure compliance with the rule.<br><br>Responsibilities shall ensure transportation operations are conducted in a manner to prevent food from becoming unsafe during transport (i.e., apply controls) and that responsibility for compliance with the regulation is assigned to competent supervisory personnel. | | |
| 38 | 13.4.3 | Where the site arranges transportation, it shall document sanitary design requirements and cleaning procedures of vehicles appropriate for the type of food to be transported. These requirements shall be communicated to the loader and carrier.<br><br>Where the site does not arrange transportation, the above provision shall be documented in the shipping service contract to ensure the shipper documents sanitary specifications of vehicles for the loader and carrier, which are appropriate for the type of food. | | |

| | | | | |
|---|---|---|---|---|
| 39 | 13.4.4 | Contracts with loaders shall specify that the loader is responsible for following sanitary specifications provided by shipper. | | |
| 40 | 13.4.5 | Where the site receives temperature controlled product immediately following transportation, it shall conduct an assessment to determine whether the food was subject to temperature abuse. | | |
| 41 | 13.4.6 | Contracts with carriers shall specify that the carrier is responsible for the following sanitary activities where agreed to in writing with shipper.<br>• Sanitary condition of vehicles and transportation equipment<br>• Following shipper's sanitary specifications (including pre-cooling requirements where applicable)<br>• Recording compliance with operating temperature where critical to food safety<br>• Procedures for the use of bulk vehicles, which includes recording the previous cargo and most recent cleaning for the shipper | | |
| 42 | 13.4.7 | Contracts with carriers shall specify that the carrier implements a training program for all personnel engaged in transportation activities, which covers<br>• Awareness of potential food safety problems that may occur during food transportation<br>• Basic sanitary transportation practices to address those potential problems | | |

| | | | | |
|---|---|---|---|---|
| | | • Responsibilities of the carrier | | |
| 43 | 13.4.8 | The site shall keep all records related to U.S. transportation operations and transportation service contracts as original or electronic records for a minimum of 12 months beyond termination of the activity or contract. Offsite records shall be retrievable within 24 hours. | | |
| 44 | 13.4.9 | The recordkeeping policy shall ensure all sanitary design requirements and cleaning procedures for vehicles are maintained onsite and all offsite records are retrievable within 24 hours. | | |
| 45 | 13.5.1 | Personnel (permanent and temporary) who handle produce or food contact surfaces must receive additional training on the following:<br>• Principles of food hygiene and food safety<br>Produce safety standards applicable to an individual's job | | |
| 46 | 13.5.2 | Personnel (permanent and temporary) who conduct harvest activities (including washing and cooling) must receive additional training on the following:<br>• Recognizing produce contaminated with known or reasonably foreseeable hazards<br>• Inspecting harvest containers and equipment to ensure that they are clean, maintained and do not contaminate produce with hazards<br>• Correcting problems with harvest containers or equipment | | |

| | | | | |
|---|---|---|---|---|
| 47 | 13.5.3 | One or more supervisors or individuals responsible for the operation must have successfully completed food safety training equivalent to standardized curriculum recognized by the FDA. | | |
| 48 | 13.5.4 | A supervisor shall be identified with responsibility for the operation and ensuring compliance with Produce Safety regulation. This individual shall be identified on the site's organizational chart. | | |
| 49 | 13.5.5 | Personnel (permanent and temporary) shall avoid contact with animals or take measures such as hand washing and protective clothing to prevent contamination of produce and food contact surfaces following contact with worker animals. | | |
| 50 | 13.5.6 | The water distribution system supplying agricultural water used for harvest, packing, holding—and associated equipment—shall be maintained, regularly inspected and equipment properly stored to prevent the system from being a source of contamination to produce and food contact surfaces. The system shall be inspected for conditions, which could introduce known or foreseeable hazards into or onto produce.<br>Where testing of the water source or system inspection reveals contamination, deficiencies shall be corrected such as the repair of well caps or sanitary seals. | | |
| 51 | 13.5.7 | Agricultural water treatment must be delivered and monitored at a frequency that ensures water is safe, of adequate sanitary quality, and meets the microbial quality criteria of no detectable generic Escherichia coli (E. coli) in 100mL. | | |
| 52 | 13.5.8 | Potable water quality standards used shall ensure the microbial quality criterion is met, which is no | | |

| | | | | |
|---|---|---|---|---|
| | | detectable generic E. coli in 100 mL. | | |
| 53 | 13.5.9 | Where agricultural water does not meet microbial quality criteria or is determined to be unsafe and not of adequate sanitary quality, water use must be discontinued along with treatment or other correction that reestablishes sanitary quality and microbial criteria.<br><br>Where water treatment is not performed, re-inspection of the entire affected agricultural water system shall be conducted followed by the identification of conditions leading to the introduction of hazards into or onto produce or food contact surfaces, correction, and verification of correction to ensure water meets microbial quality criteria. | | |
| 54 | 13.5.10 | Agricultural water testing may be performed by the site (or site representative) or by a third party provided representative samples of the site's water source is secured.<br><br>Aseptic water sampling must be performed. The method of analysis for water testing is U.S. Environmental Protection Agency (EPA), "Method 1603: Escherichia coli (E. coli) in Water by Membrane Filtration Using Modified membrane-Thermotolerant Escherichia coli Agar (Modified mTEC), EPA–821–R–09–007)," December, 2009 or equivalent method. | | |
| 55 | 13.5.11 | During harvest, packing and holding operations (e.g., hydrocooling, washing), manage water to maintain its safety and sanitary quality and prevent contamination of produce to include establishing and following a water-change schedule for recirculated water.<br><br>Visually monitor the water quality of water used for harvest, packing, | | |

| | | | | |
|---|---|---|---|---|
| | | and holding activities for organic build-up (e.g., soil, plant debris).<br>Maintain and monitor the temperature of water used for harvest, packing, and holding activities as appropriate to the commodity and operation to minimize infiltration of pathogens into produce. | | |
| 56 | 13.5.12 | Dropped produce (i.e., produce that comes in contact with the ground prior to harvest) where the produce would not normally touch the ground as a part of growing and harvest (e.g., cantaloupe, almonds, etc.) shall not be distributed. | | |
| 57 | 13.5.13 | Sewage disposal and septic systems shall be controlled and appropriate for the site to prevent the contamination of produce and food contact surfaces. | | |
| 58 | 13.5.14 | Plumbing shall not allow backflow or cross-connection between waste and potable water lines. | | |
| 59 | 13.5.15 | All produce safety related records must be reviewed, dated, and signed within a reasonable timeframe after being made by the supervisor or responsible party. | | |
| 60 | 13.5.16 | All produce safety documents and records must be retained at the site for 2 years after the record is created.<br>Where records are stored offsite, they must be retrievable within 24 hours.<br>Records related to equipment or processes used by the site for analyses, sampling, or action plans—including the results of scientific studies, tests, and evaluations—shall be retained at the site for at least 2 years after their use is discontinued. | | |

| | | | | |
|---|---|---|---|---|
| 61 | 13.5.17 | Specific additional requirements for the harvesting, packing, and holding of sprouts.<br><br>Establish and implement a written Environmental Monitoring plan for the testing of Listeria spp or Listeria monocytogenes.<br><br>The environmental monitoring plan shall include the following criteria:<br>• Target test (i.e., Listeria spp. or L. mono)<br>• Sample frequency (no less monthly)<br>• Sample timing (i.e., when in the process are samples collected)<br>• Sample sites where the number of samples and location are sufficient to determine the efficacy of controls (includes food contact and non-food contact surfaces)<br><br>The plan shall describe aseptic methods for sample collection and testing according to FDA's "Testing Methodology for Listeria species or L. monocytogenes in Environmental Samples," Version 1, October 2015 (or equivalent). | | |
| 62 | 13.5.18 | Specific additional requirements for the harvesting, packing, and holding of sprouts.<br><br>The environmental monitoring plan shall include a corrective action plan if any samples are positive for Listeria spp. or L. mono.<br><br>If Listeria spp. or L mono are identified in the harvesting, packing, holding area, the following activities shall occur as a part of the corrective action process:<br>• Resample positive surfaces and the surrounding area to | | |

| | | | | |
|---|---|---|---|---|
| | | determine the extent of contamination<br>• Clean and sanitize the affected and surrounding areas<br>• Resample and re-test to confirm the elimination of Listeria spp. or L. mono<br>• Conduct finished product testing as appropriate<br>• Take additional action to prevent recurrence and to prevent adulterated food from entering commerce | | |